II. REMARKS

A. Status of the Claims

Claims 6, 13, 14, and 24 have been amended without prejudice.

New claims 31 to 38 have been added.

Support for the amended and new claims can be found throughout the specification and in the original claims. Specifically, support for C_{max} values recited in these claims can be found, e.g., in Examples 5-10. Support for "C_{24}" value in claims 32 and 34 can be found, e.g., on page 32, line 15, of the application as filed. Support for "C_{max}" value in claims 31, 33, 36, and 38 can be found, e.g., in Table 14 of the application as filed.

Claims 1-5, 9-12 and 17-23 were previously cancelled without prejudice.

Claims 6-8, 13-16 and 24-38 are pending.

Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Claim rejection under 35 U.S.C. §103

In the Office Action, the Examiner maintained the rejection under 35 U.S.C. §103(a) of claims 6-8, 13-16 and 24-30 over Goldie et al. (U.S. 4,844,909). The Examiner stated that Applicants' arguments (i.e., arguments directed to the limitation "such that the tablet attains a dissolution profile which is substantially unaffected by exposure to storage conditions of at least a month at a temperature of 40° C and a relative humidity of 75%") are not persuasive "because Applicant has failed to sufficiently prove that dissolution release profiles change on ageing is indeed an art recognized problem." *Office Action, page 6.* The Examiner concluded that "any

dissolution profiles will be viewed as inherent properties of the same composition as instantly claimed." *Id.*

Applicants respectfully traverse the Examiner's rejection. It is respectfully submitted that the Goldie reference does not describe the same composition as recited in the present case, at the very least because the Goldie reference does not describe a hydromorphone formulation comprising "a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer" as recited in the present claims.

In fact, in every instance that the Goldie reference mentions incorporation of a hydrophobic polymer into the dosage forms described therein, it is always in conjunction with an organic solvent (e.g., methanol 60 % v/v; *see, e.g., the Goldie reference, Example 4*) or a higher aliphatic alcohol. Accordingly, it is submitted that there is no teaching in the Goldie reference to use water in connection with hydrophobic polymers to form an aqueous dispersion of these polymers. Therefore, the premise that the Goldie reference describes the same composition as presently claimed is incorrect, as there is no description in the Goldie reference of an aqueous dispersion of a hydrophobic polymer, let alone a description of "a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer" as recited in the present claims.

Applicants note that "a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer" as recited in independent claims 6 and 24 results, e.g., in a dosage form that provides "a dissolution profile which is substantially unaffected by exposure to storage conditions of at least one month at a temperature of 40°C and a relative humidity of 75% dissolution profile." *See, e.g., Table 10, 11 and 12.*

Applicants further submit that there is simply no support in the Goldie reference for the Examiner's assertion that the compositions of the Goldie reference would inherently (i.e., necessarily) possess the same characteristics as recited in the present claims, as the compositions

of the Goldie reference are different from the compositions recited in the present claims, at the very least for the reasons set forth above.

In any event, to advance the prosecution of the present case, independent claims 6 and 24 have been amended without prejudice to recite in part that "the dosage form ... providing a mean C_{max} of hydromorphone from about 1070 pg/ml to about 1721 pg/ml and a T_{max} of between 4.4 to 8 hours."

Applicants submit that the Goldie reference does not suggest to one skilled in the art to pick the specific C_{max} values recited in the present claims out of a theoretically infinite number of possibilities. It should be noted that the mean plasma concentrations (e.g., at 1.5 hours, 2.0 hours, 2.5 hours, 3.0 hours, 4.0 hours, 6.0 hours) of the exemplified formulations of the Goldie reference are much higher than the C_{max} values recited in independent claims 6 and 24. *See, Goldie reference, Tables 5 and 6.* Accordingly, it is respectfully submitted that these formulations do not and cannot provide the specific C_{max} values recited in the present claims.

Applicants further submit that the Goldie reference does not suggest to one skilled in the art a dosage form providing both the specific C_{max} values and the specific T_{max} values recited in the present claims.

Accordingly, Applicants submit that the Goldie reference does not render obvious the methods of claims 6 and 24, and respectfully request withdrawal of the obviousness rejection over the Goldie reference.

With regard to new claims 32 and 34, Applicants submit that the Goldie reference does not suggest a dosage form providing "a mean C_{24} of about 600 pg/ml" as recited in these claims.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is specifically authorized to contact the undersigned by telephone in the event a telephone interview would advance the prosecution of the application.

Respectfully submitted,
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